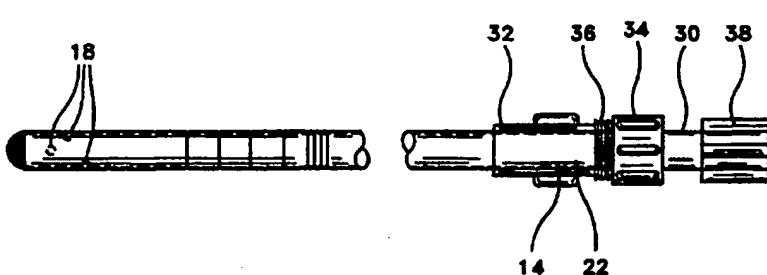


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(54) Title:	A CATHETER HAVING WALL SUPPORT TO PREVENT COLLAPSE THEREOF		
(57) Abstract	<p>A catheter having wall support to prevent occlusion or kinking, particularly due to constriction by a medical adaptor retained at the proximal end thereof. The catheter can be formed from a soft material such as polyurethane so as to minimize traumatic effect to the body. A coil spring element is incorporated about the passageway of the catheter at the proximal end. The length of the coil spring is preferably matched to the length of the catheter subject to constriction by the adaptor, thereby preserving good visibility of fluid through the catheter while providing anti-occlusion support where most needed. If desired, the major length of the catheter can be provided with a structuring or profiling treatment so as to provide anti-kinking resistance along the length of the catheter while retaining the benefits of a soft material.</p>		
			

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## A CATHETER HAVING WALL SUPPORT TO PREVENT COLLAPSE THEREOF

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### I. Field of the Invention.

This invention relates to a device for averting the collapse of the walls of a catheter, and more particularly, to a catheter having wall support to prevent collapse or kinking and being adaptable for use with standard medical adaptor and delivery instruments and accessories.

### II. Background

In recent years, there has been a marked increase in the use of catheters by physicians conducting various medical procedures and especially surgical procedures. Catheters are typically elongate tubes formed from medical grade plastics made as polyethylene, polyimide, or even nylon, which define fluid carrying ducts for transporting a medicament from a delivery instrument to body tissue. They are typically introduced into the body cavity through the lumen of a needle or introducer device already pierced into the body. Thereafter, the needle or introducer is threadedly removed about the catheter without displacing the catheter from position within the body. One use of a catheter is found in providing continuous regional anesthesia, and is exemplified, for instance, by the use of epidural catheters to deliver anesthesia to the epidural space of a patient. Catheters are also used for analgesic purposes to provide sustained pain relief following a surgical procedure. Here, the catheter is kept in place following the procedure and analgesic medicaments administered intermittently according to the needs of the patient.

The nature of uses for the aforementioned catheters dictate that dimensions, materials, and other characteristics be selected so as to promote

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their effective use with minimal trauma or intrusive reaction to the patient. For instance, the outside dimensions of the catheter normally are reduced to as small a diameter as possible so as to minimize the intrusive effects of the catheter to body tissue. Attention must be also paid to the type of material employed for constructing the body of the catheter. In general, catheters such as intended for epidural anesthesia can be formed from a stiff material such as nylon or a soft material such as polyurethane. Both types of materials present certain advantages and certain drawbacks. In a study conducted by M. Jöhr, F. A. Hess, S. Balogh and H. Gerber, "The choice of the epidural catheter: stiff or soft?" (Regional Anesthesia, Volume 17, No. 3S, May-June 1992 Supplement), "stiff" versus "soft" catheters were compared against a number of parameters including difficulty of insertion, sufficiency of the block provided by the catheter, blood aspiration problems, and paraesthesia. In general, it was found that a stiffer catheter might be preferred in view of its easier insertion into the body, but that such catheters provided greater instances of complications including paraesthesia and blood aspiration. Similar conclusions were reached by S. Rolbin, E. Hew, and G. Ogilvie in "A comparison of two types of epidural catheters," Can. J. Anaesth., 1987, 34:5 pp. 459-61. The latter mentioned difficulties such as paresthesia often lead practitioners to prefer catheters made from a softer material so as to minimize trauma caused to the body.

Owing to considerations of diameter and material choice, catheters such as epidural catheters are often prone to kinking or occlusion problems. Kinking and occlusion problems frequently occur at points subject to external pressures such as where a catheter is attached to an injection port site (P. de Long and P. Kansen, "A Comparison of Epidural Catheters With or Without Subcutaneous Injection Ports for Treatment of Cancer Pain," Anesth. Analg., 1994, 78: 94-100). In practice, kinking also frequently occurs at the proximal end of the catheter when, for instance, a standardized medical connector such as a Tuohy-Borst adapter is attached for mating with a medical delivery device such as a syringe. As is well known, the Tuohy-Borst adapter includes a gasket portion which applies pressure about the circumference of the catheter. The pressure exerted at or near the proximal end can cause the catheter walls to collapse upon themselves so as to constrict if not eliminate flow of the medicament from

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the medical delivery device through the catheter. In view of the exigencies of the operating environment, the need to provide the patient with as rapid and efficient an epidural block as possible, the time constraints on operating room facilities, and the like, such problems cause major difficulties to both patient and medical personnel and they merit address.

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Numerous attempts in the art have sought to address the aforementioned concerns. For instance, U.S. Patent Nos. 4,985,022 and 5,069,674, both to Fearnott et al., disclose flexible kink-resistant catheters employing, as a primary component, a section of tightly wound wire coil within the fluid duct and about some length of the catheter. These coils appear to be merely stretched to be insertable into the fluid duct, so that they will remain on the surface of the duct and held in place by friction fit. Certain of these approaches also require additional elements within the flow duct in an attempt to render laminar turbulent flow characteristics imparted by the coil. In the '022 patent, the coil is wound in a section at or near the distal tip of the catheter, while in the '674 patent it appears that the wire coil is displaced along substantially the entire length of the catheter. The '022 patent further employs a "durable catheter" segment proximally of the wire coil catheter segment which has a stainless steel tube formed of a flat wire coil that surrounds the length of the tube. A similar approach is taken by Arrow International, Inc. in its "Flex-Tip Plus<sup>TM</sup>" epidural catheter, which features a catheter having a tightly wound wire coil in the fluid duct substantially along the entire length of the catheter and is sold with its own proprietary adaptor device in lieu of a standardized adaptor such as a Tuohy-Borst adaptor.

While serving to minimize catheter diameters somewhat and address certain kinking problems along the length of the catheter, none of these approaches is entirely satisfactory. A first problem is that it is believed that the presence of a metallic component throughout substantially the entire length of the catheter contributes to difficulties with paraesthesia in the patient. Electrical shocks can be transmitted through the metallic component to affect nerve roots coming in contact with any portion of the catheter, and in particular those in proximity to the distal tip of the catheter.

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5           A second problem is that the practitioner's ability to discern fluid flow through the catheter is impeded by the presence of the largely opaque metallic component along the entire visible length of the catheter. While certain catheters, such as the Arrow Flex-Tip Plus™, incorporate areas of reduced coil windings (so as to open semi-transparent "windows" through the length of the coil), the large majority of the catheter is still opaque and impedes easy view for the practitioner. This is particularly detrimental in that practitioners oftentimes need to detect certain difficulties, such as blood aspiration, in as rapid a manner as possible.

10          Another problem is that the presence of coils within the interior portion of the catheter tends to constrict fluid flow through the length of the catheter. While the aforementioned approaches indicate that the interior diameters of the coil are such that fluid flow will not be impeded, in reality the presence of a foreign object within the duct of the catheter will, to some extent, reduce 15 overall fluid flow rate, while increasing the velocity of the fluid flowing through the duct and elevating the exit pressure, all of which can be detrimental to the patient. An ancillary difficulty is that the presence of coils traverse to the direction of flow in the duct tends to create turbulent flow characteristics for the medicament being injected. Turbulent flow is preferably avoided in catheter practice, in that a practitioner will have less control in directing medication ejected through the distal tip. Thus, the practitioner's ability to direct a more 20 precise block in the epidural space is reduced. The task is much easier to accomplish if fluid flow is laminar when exiting the tip of a catheter.

25          A further problem is that the presence of a coil along the entire length of a catheter typically necessitates that the catheter be formed with an open distal end. In practice, it has been found that doctors oftentimes prefer closed-ended catheters. Closed-ended catheters are typically provided with circumferential ports adjacent the distal end of the catheter for emitting the fluid medicament into the body tissue. Practitioners have found that with the latter construction, 30 a more uniform flow is provided and that it is easier to direct the flow of anesthetic to a specific point so as to provide a deeper and more precise block. Studies have also found that open-ended catheters may be more traumatic to tissue and, hence, could be more difficult and more painful to place in the tissue

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than close-ended catheters. See, for instance, S. Michael, M.N. Richmond, and R.J.S. Birks, "A Comparison between open-end (single hole) and closed-end (three lateral holes) epidural catheters", Anaesthesia, 1989, Vol. 44 pp. 578-580.

5 One solution to implementing a closed-end tip with a coil construction would be to terminate the coil before the distal end of the catheter so as to form the closed end from the catheter material. Another would be to drill through the coils to establish the circumferential ports. However, the interface formed between the end of the coil and the catheter body (or at the point the hole is drilled through the coil) would create stress concentrators which would weaken  
10 the catheter in that area. There is the disconcerting potential that the catheter would break-off in that area, frequently lodging within the body of the patient. These concerns also affect catheters which include integrally-attached metal stylets located in the interior of the duct or in the catheter wall. If the stylet is  
15 bent or damaged there is a better likelihood that the catheter will break. See S. Ley and B. Jones "Strength of Continuous Spinal Catheters", Anesth. Analg. 1991, 73:394-6. While it has been suggested that the harm caused by surgical intervention in removing a broken catheter segment outweighs the relative  
20 harmlessness in allowing the piece to remain in situ, it has been acknowledged that presence in the body of catheters with metallic elements will inhibit patients from being able to utilize certain diagnostic procedures such as magnetic resonance imaging ("MRI's"). See Ronald H. Lambert, "Continuous Spinal Anesthesia" in Postoperative Pain Management (Michael F. Ferrante, Editor),  
25 pp. 342-343 (New York: Churchill Livingstone 1993).

25 One solution to strengthening the proximal end of the catheter would be to incorporate some type of rigid cylindrical plug element at or about the proximal end so as to prevent construction by an adaptor element. However, this approach is less than satisfactory as a rigid element tends to establish a stress concentration along the catheter body, rendering the catheter prone to  
30 breakage. Moreover, rigid elements are prone to interference with the tips of the introducers or needles as they are threadedly removed about the catheter. This is particularly true of needles such as epidural needles which tend to

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exhibit curved distal tips, which rigid elements are less prone to maneuver about.

There exists a need, therefore, for a catheter construction which prevents kinking along its length, particularly at the point where an adapter is connected to the catheter, which preserves the strength of the catheter as well as the integrity of the catheter in the body, which provides the practitioner with a ready view of the fluids flowing through the catheter, which largely addresses problems such as paraesthesia and trauma to the patient, and which in whole addresses the problems experienced by previous approaches.

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#### SUMMARY OF THE INVENTION

These and other concerns are addressed by a catheter according to the present invention. While the principles of the present invention are described with particular reference to a catheter, it will be readily apparent and fully appreciated by the skilled artisan that the principles herein discussed can be readily applied to any tube or similar element subject to constriction by an adaptor-type device.

Accordingly, the catheter may be formed from a soft material such as polyurethane to minimize traumatic effects to the body. The catheter features a proximal end adapted to be retained by a medical adapter such as a Tuohy-Borst adapter together with a major length adapted for insertion into the body cavity of a patient. The proximal end of the catheter may be configured to resist the pressures exerted by the adapter so as to prevent collapsing or kinking of the catheter. In one embodiment, a section of coiled wire tubing may be fixedly bonded to the catheter such as by chemical adhesives, ultrasonic welding, heat welding (heat staking) or RF welding. The coil is disposed about the interior of the catheter substantially adjacent to a section of the catheter which will be subject to forces exerted by the adapter. The wire coil enhances the structural integrity of the catheter against collapse while averting prior problems to the patient such as paraesthesia. The bonding process may result in the coil being incorporated into the wall of the catheter so as to eliminate the

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presence of the coil in the fluid duct and provide a substantially uniform flow duct within the catheter. Thus, the need for additional elements to render laminar turbulent flow characteristics is largely obviated. If desired, the diameter of catheter wall section to be strengthened can be configured apart from the rest of the catheter so as to compensate for any diametral or flow constrictions imposed by the presence of the coil about the outer catheter duct. Alternatively, if desired, the coil may be formed about the circumference of the catheter, or it may be incorporated as part of the medical adaptor.

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The remaining length of the catheter may be strengthened by structuring techniques to prevent collapsing and/or kinking during use. For instance, in one embodiment, the catheter may be strengthened by structuring the interior with a profile to prevent kinking problems along the length. For instance, the profile can constitute forming the interior of the catheter with rib elements. Alternatively, the catheter may be structured with a form-specific profile or cross-section such as a star-shaped cross-section. This approach prevents the hindrances of extraneous inserts in the flow of fluid. Because the structuring is largely parallel to the flow path, the probability of turbulent flow is significantly reduced. A closed-ended distal tip may be readily incorporated and circumferential ports provided for the exit of fluids.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in greater detail by way of reference to the following drawings, wherein:

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Fig. 1 depicts a longitudinal cross-sectional view of one embodiment of a catheter according to the present invention;

Fig. 2 is a cross-sectional view taken along line 2-2 of Fig. 1;

Fig. 3 depicts a second longitudinal cross-sectional view of the embodiment of Fig. 1 shown in conjunction with a medical adaptor device;

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Fig. 4 is a side view of a catheter wall support device as employed in the present invention;

Fig. 5 is an end view of the catheter wall support device depicted in Fig. 4;

**Fig. 6 depicts the catheter of the present invention incorporating a wider-diameter proximal end to accommodate a catheter wall support device; and**

**5 Fig. 7 illustrates a structured cross-section for the interior duct of the catheter of the present invention.**

DETAILED DESCRIPTION OF THE INVENTION

Turning now to the drawings, wherein like numerals denote like components, Figs. 1-7 depict one embodiment of an anti-kinking catheter 10 in accordance with the present invention. In this embodiment, the catheter 10 includes a distal end 12 having a closed end 20, a proximal end 14 having a catheter wall support device 22, and a major length 15 is adapted for insertion into a body cavity during a medical procedure. The catheter 10 may be formed from any number of medical grade materials such as nylon. In a preferred construction, the catheter 10 is formed from a soft material such as polyurethane so as to minimize traumatic effect to the body and provide the practitioner with a clear view of fluid flow through the catheter 10. As also illustrated, a plurality of circumferential side port openings 18 may be formed at or about the distal end 12 of the catheter to provide for the exit of fluid introduced via the proximal end 22 of the catheter. The outside diameter ("OD") of the catheter 10 may be dimensioned in any of the standard medical gauges most appropriate or readily used for the intended application. For instance, for an epidural catheter, the OD can be established, as per the conventional sizing typically used by practitioners, to 19 gauge (approximately 0.043"), 20 gauge (approximately 0.035"), or even 24 gauge (approximately 0.022").

A catheter wall support device 22 is incorporated at the proximal end 14 of the catheter and is snugly retained about the fluid duct 40, which is defined by an inner diameter "y". The coil spring 22 can be retained to the catheter, *inter alia*, by chemical adhesives, ultrasonic welding, heat staking or RF welding. The support device 22 may have a length "x" of between, for example, 1/8" to 1/2", depending upon the type of adapter such as a Tuohy-Borst adapter 30, which is attached to the proximal end 14. A Tuohy-Borst adapter 30, such as depicted in Fig. 3, includes a gasket portion 32 having a plurality of threads 36 engageable by a nut 34 actuated by a knob 38. Thus, as knob 38 is rotated, nut 34 is advanced distally along the threads 36 to exert pressure upon the gasket 32. Hence, retentive force will be applied to the proximal end 14 of the catheter so as to retain the catheter within the adapter. The support device 22 will prevent collapse and/or occlusion of the catheter.

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when the force is applied by the gasket 32, so as not to impede fluid flow through the catheter 10. The length "x" of the coil spring 22 should be matched to and be at least as long as the length 32 of the adaptor gasket, lest a portion of the gasket be allowed to exert force upon an unsupported portion of the catheter to cause occlusion or kinking in a manner previously described.

In one embodiment, the support device 22 may be formed as coil spring, as best depicted in Figs. 4 and 5. The spring 22 may be formed, for instance, from AISI Type 304 stainless steel. In one configuration, the spring 22 may be wound from a wire having a diameter "a" of about 0.003" to form a plurality of active coil turns 42. For a coil spring 22 having a length "x" of about 0.500"  $\pm$  0.015", the numbers of active coil turns 42 can be, for instance, 25. For the gauges of catheters which can be formed, the coil spring may define an outer diameter "d" of about 0.016"  $\pm$  0.001" and an inner diameter "c" of about 0.010".

The advantages of employing a coil spring 22 over other types of catheter wall support, such as a tubular metal or plastic tube or plug, are many. The spring 22 may be bonded to the catheter 10 with various medical grade adhesives. In one preferred practice, the spring 22 is heat stake welded or RF welded within duct 40 about the interior of the catheter 10, lessening the possibility that a chemical adhesive bonding element can adversely react with the medicaments introduced through the catheter 10. The spring 22 will thus be fixedly secured to the catheter so as to bond the coil spring 22 to the catheter 10. Depending on the duration of the heat or RF treatment and catheter materials employed, the catheter material may flow around the spring coils 42, thereby embedding the coil within the catheter wall, such that the catheter duct 40 will be substantially uniform along its entire length without disruption by an intrusive element in the duct 40. This contributes significantly to ensuring smooth, laminar flow about the entire length of the catheter. Note also that because the spring 22 is more flexible than a solid tube or plug, the proximal end 14 of the catheter is less prone to interference with the curved distal tips of epidural needles or introducers when those instruments are threadedly removed about the catheter, thus making the catheter less prone to being "caught" on the epidural needle when the needle is being removed.

(11)

following catheter placement in the body cavity. Moreover, as the coil is more free to flex along its length than a rigid element such as a tubular metal or plastic plug, the spring 22 is better able to distribute stresses and forces and can largely avoid the creation of a stress concentrator (for instance, at the interface 5 between the end of the coil and the catheter itself) which could lead to breakage.

Note that with the approach taken herein, the coil spring is disposed only adjacent the proximal end of a catheter 10 and in particular, only at the location subject to retention by the adapter 30, so as to provide anti-kink protection in the area where most needed. However, the problems caused by a 10 coil spring disposed throughout the entire length of the catheter in accordance with prior teachings in the art, such as traumatic effects, paraesthesia, or the ability to form a closed-end catheter with good strength properties, are largely avoided because no metal is present in the substantial length of the catheter.

As depicted in Figure 6, if desired, the intrusive effects of the coil spring 15 22 placed within the duct 40 of the catheter can be further minimized, if not completely eliminated, by forming the proximal end 14 of the catheter slightly wider than the rest of the length of the catheter in order to accommodate the diametral width of the coil spring 22 therein. In essence, the larger catheter 20 width provides for a substantially smooth interface between the coil spring and the remainder of the duct 40 of the catheter 10. In addition, fluid is free to flow without interruption at a stepped interface between the spring and the catheter duct, reducing the instance of turbulent flow characteristics and contributing to laminar flow throughout the length of the conduit of the catheter 10.

It will also be appreciated and understood by the skilled artisan that if 25 desired, the spring 22 can be appropriately dimensioned so as to be incorporated about the outside circumference of the catheter 10, rather than in the interior such as within duct 40. The coil can be affixed to the catheter such as by heat welding or RF welding in a manner previously described, so as to 30 enjoy the benefits previously noted. Note here that the presence of an intrusive element within the flow duct is completely obviated. Also, if desired, the spring 22 can be incorporated as part of the adaptor 30 itself, for instance, at or about the gasket portion 32, with the proximal end of catheter 10 engaged within the

gasket 32/coil spring 22. The presence of the spring 22 about the outside surface of the catheter 10 substantially prevents constriction of the catheter in a manner previously noted.

It will be appreciated and understood by the skilled artisan that the length of the catheter 10 and in particular, the major length 15 comprising the portion to be manipulated and/or inserted into the body cavity, can be provided with a profiling or structuring treatment along the duct 40 so as to enhance the overall anti-kinking properties of the catheter. The structuring treatment strengthens the catheter 10 against kinking or occlusion problems while at the same time permitting a softer material to be employed in forming the catheter. For instance, the catheter 10 may be extruded so as to include a profiling treatment such as longitudinal ribs running along the length of the catheter, either outside the catheter or, so as to minimize trauma to the patient, forming ribs on the interior cross-section of the catheter. Alternatively, the catheter 10 may be formed or extruded with a shaped duct cross-section designed to enhance the catheter's ability to resist occlusion if bent. In one configuration, as depicted in Figure 7, the catheter can be formed with a star-shaped cross-section configuration. Even if the catheter 10 is bent along its length, the interspaces 60 defined between the star points (or ribs, if so configured) will permit fluid to pass through the duct 40 to the distal end 12. Moreover, because the material can be chosen for its clarity properties, practitioners are still provided with an unimpeded view of the medicament flowing through the catheter.

Thus, it will be seen that the catheter according to the present invention addresses many of the drawbacks exemplified by the prior art approaches. The catheter displays anti-kinking properties substantially along its entire length, while not obscuring the view of the practitioner during use and permitting the catheter to be formed from a relatively soft material and with a closed ended construction so as to minimize traumatic effects to the patient. The construction also contributes to overall strength and integrity of the catheter along its entire length. In addition, laminar flow is provided over the length of the duct, permitting the practitioner to better provide a more precise and effective block.

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**It will be appreciated and understood by those skilled in the art that further and additional forms of the invention may be devised without departing from the spirit and scope of the appended claims, the invention not being limited to the specific embodiments shown.**

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**WHAT IS CLAIMED IS:**

1. A catheter having anti-kinking properties,  
said catheter defining a passageway therethrough for transport of a fluid  
from a medical delivery instrument to a body cavity and having a proximal end,  
a distal end, and a major length therebetween adapted for insertion into said  
body cavity, said catheter including a support device fixedly attached about the  
passageway at said proximal end and having a length approximately equal to  
the length of the catheter subject to constriction by an adaptor attached thereto.
- 10 2. The catheter of Claim 1, wherein said support device comprises  
a coil spring.
- 15 3. The catheter of Claim 1, wherein said major length includes a  
plurality of integrally formed support elements longitudinally disposed within  
said passageway for averting kinking of said major length.
- 20 4. The catheter of Claim 3, wherein said integrally-formed support  
elements comprise ribs.
- 25 5. The catheter of Claim 3, said passageway having a substantially  
star-shaped cross-section, said cross-section defining said integrally-formed  
support elements.
- 30 6. The catheter of Claim 2, wherein said coil spring is heat welded  
to said catheter.
7. The catheter of Claim 6, wherein said coil spring is substantially  
embedded into the wall of said catheters, wherein the surface of said  
passageway is substantially uninterrupted by said coil spring.
8. A catheter assembly having anti-kinking properties, comprising:

(15)

- a catheter component defining a passageway therethrough for transport of a fluid from a medical delivery instrument to a body cavity, said catheter having a proximal end, a distal end, and a major length therebetween;
- 5           a coil spring bonded within said passageway adjacent the proximal end said coil spring having a length approximately equal to the length of said catheter subject to constriction by an adaptor attached thereto,
- wherein said major length defines a structural cross-section in said passageway for supporting said major length against kinking.
- 10           9. The catheter of Claim 8, wherein said distal end is closed, said catheter including a plurality of openings disposed about the circumference of the catheter adjacent the distal end to permit the exit of fluid.
- 15           10. The catheter of Claim 8, wherein said proximal end is formed slightly wider than the rest of said catheter, said wider proximal end accommodating said coil spring therein to provide a substantially uniform passageway along the substantial length of the catheter.
- 20           11. A catheter assembly having anti-kinking properties, comprising:
- a catheter component defining a passageway therethrough for transport of a fluid from a medical delivery instrument, said catheter having a proximal end, a distal end, and a major length therebetween;
- a medical adaptor configured to snugly retain said catheter therein;
- a coil spring disposed about the passageway of said catheter adjacent the proximal end to avert occlusion thereof;
- 25           said coil spring having a length approximately equal to the length of the catheter subject to constriction by said adaptor.
- 30           12. The catheter of Claim 11, wherein said coil spring is incorporated at the proximal end of the catheter.
13. The catheter of Claim 11, wherein said coil spring is incorporated in said medical adaptor.

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14. The catheter of Claim 11, wherein the major length of said catheter defines a structural cross-section in said passageway for supporting the major length against kinking.

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15. The catheter of Claim 14, wherein said structural cross-section is star-shaped.

FIG-1

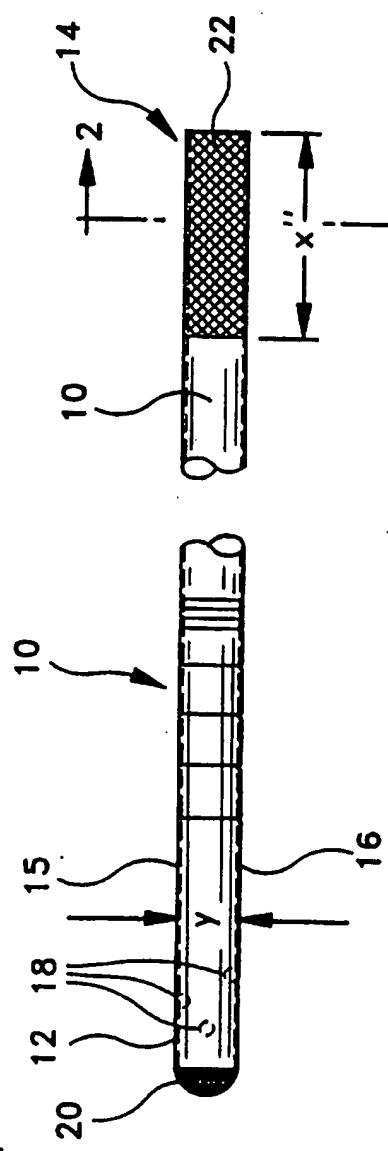


FIG-2

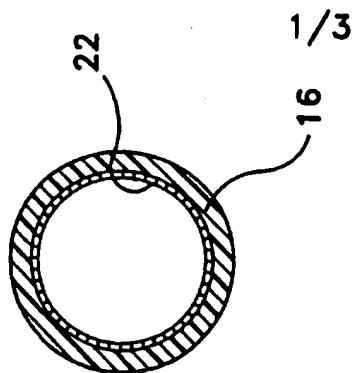
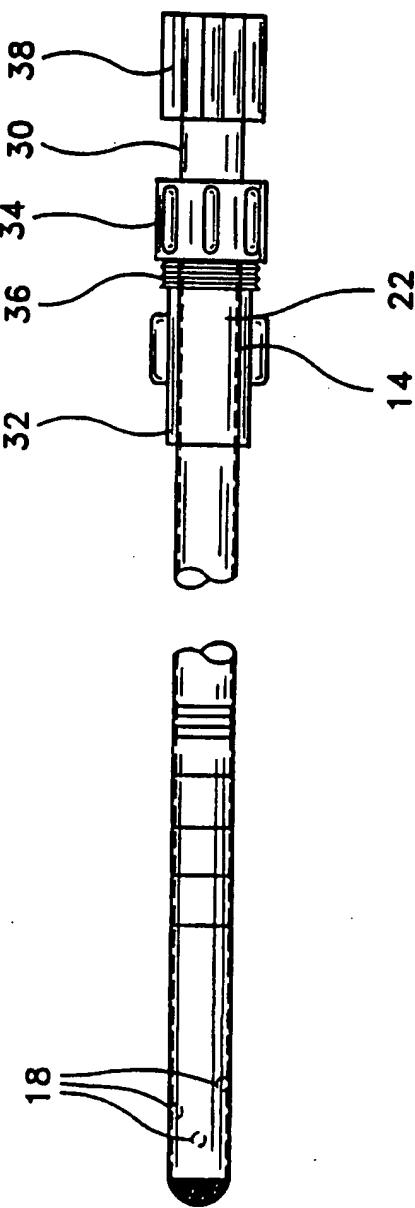


FIG-3



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FIG-5

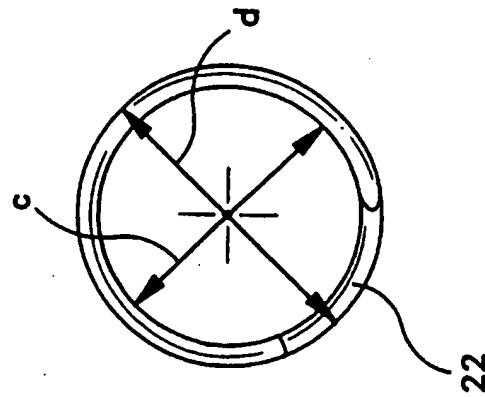
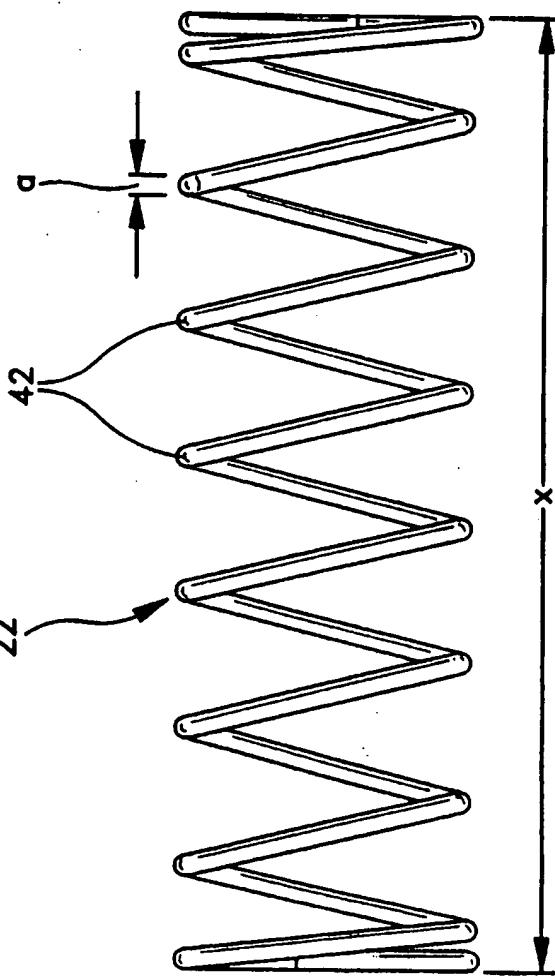
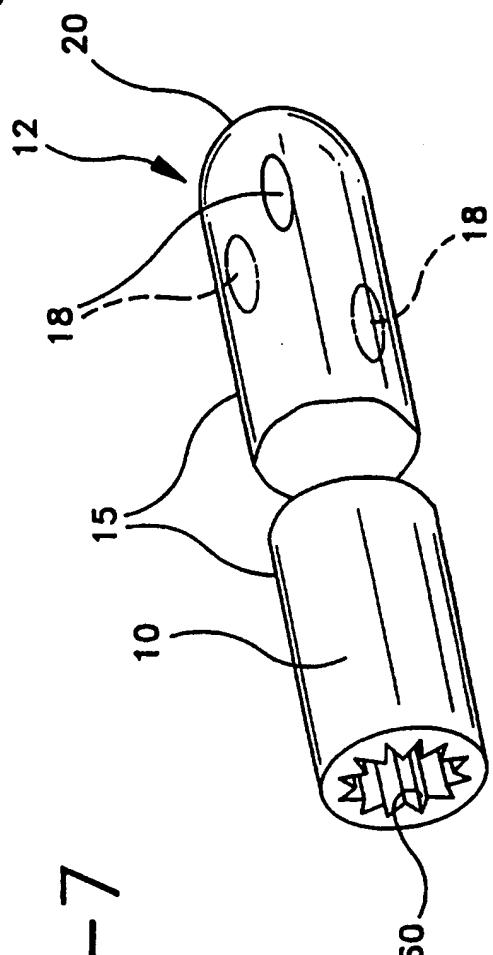
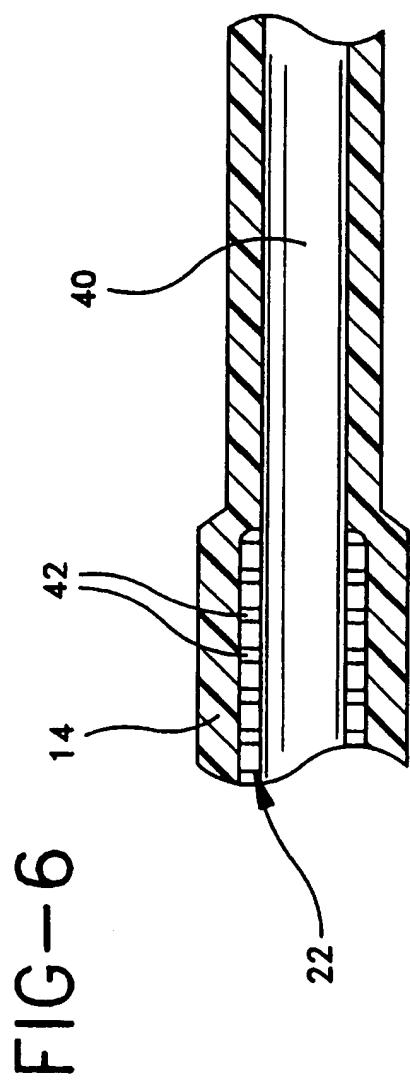


FIG-4



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# INTERNATIONAL SEARCH REPORT

Interr. Application No  
PCT/US 95/14865

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR,A,2 607 707 (L.P.I.) 10 June 1988 see page 4, line 14 - page 6, line 3 see figure 1	1
Y	---	2-4,8, 11,12
Y	US,A,4 634 432 (KOCAK) 6 January 1987  see column 1, line 32 - line 35 see column 4, line 39 - line 55 see figures 1,2	2,8,11, 12
Y	---	3,4,14
A	FR,A,2 655 548 (VAN CLEEF) 14 June 1991 see page 1, line 2 - page 2, line 12 see figure 1	5,15
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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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1 Date of the actual completion of the international search

1 March 1996

Date of mailing of the international search report

07.03.96

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## INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 95/14865

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,92 07507 (BOSTON SCIENTIFIC CORP.) 14 May 1992 see page 7, line 5 - page 10, line 23 see figures 3,4	1,2,11, 12
A	---	10
X	EP,A,0 440 426 (C.R. BARD IRELAND LIMITED) 7 August 1991 see page 1, line 15 - line 54 see figures 1,2	11,13
Y	---	14
A	DE,A,19 33 802 (SHERWOOD MEDICAL INDUSTRIES) 2 January 1970 see figure 4	9
A	US,A,4 790 831 (SKRIBISKI) 13 December 1988 see figure 3	5,15
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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

Inte... val Application No

PCT/US 95/14865

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
FR-A-2607707	10-06-88	NONE		
US-A-4634432	06-01-87	US-A- 4705511 US-A- 4657772	10-11-87 14-04-87	
FR-A-2655548	14-06-91	NONE		
WO-A-9207507	14-05-92	US-A- 5178158 CA-A- 2094371 EP-A- 0555364 JP-T- 6502565	12-01-93 30-04-92 18-08-93 24-03-94	
EP-A-440426	07-08-91	IE-B- 63252 DE-D- 69111476 DE-T- 69111476 JP-A- 7047132 US-A- 5203774	05-04-95 31-08-95 08-02-96 21-02-95 20-04-93	
DE-A-1933802	02-01-70	GB-A- 1269405	06-04-72	
US-A-4790831	13-12-88	NONE		